Queensland

Gene Technology Amendment Regulation (No. 1) 2007

Subordinate Legislation 2007 No. 45

made under the

Gene Technology Act 2001

Contents

1 Short title

This regulation may be cited as the *Gene Technology Amendment Regulation (No. 1) 2007*.

2 Commencement

This regulation commences on 31 March 2007.

3 Regulation amended

This regulation amends the *Gene Technology Regulation 2002*.

4 Amendment of s 4 (Techniques not constituting gene technology)

Section 4, from 'somatic'—

omit, insert—

'a technique mentioned in schedule 1A.'.

5 Amendment of s 5 (Organisms that are not genetically modified organisms)

Section 5, ', part 1'—

omit.

6 Amendment of s 6 (Dealings exempt from licensing)

Section 6(1)(c) and (d)—

omit, insert—

'(c) it is conducted in accordance with applicable technical and procedural guidelines, as in force from time to time under section 27(d) of the Act, about—

(i) containment of the GMO; and

(ii) if the dealing involves transporting the GMO—transport; and

(d) it does not involve an intentional release of the GMO into the environment; and

(e) it does not involve a retroviral vector that is able to transduce human cells.'.

7 Replacement of s 7 (Application for licence—prescribed information)

Section 7—

omit, insert—

'7 Application for licence—prescribed fee

Note 1—

At the commencement of this section, no application fee is prescribed under section 40(6) of the Act.

Note 2—

This section differs from regulation 7 of the Commonwealth regulations.'.

8 Amendment of s 9 (Prescribed authorities)

Section 9(a), (d) and (e)—

omit, insert—

'(a) Food Standards Australia New Zealand;

(d) the director, National Industrial Chemical Notification and Assessment Scheme;

(e) Australian Pesticides and Veterinary Medicines Authority;'.

9 Amendment of s 10 (Risk assessment—matters to be taken into account)

(1) Section 10(1)(a)—

omit, insert—

'(a) subject to section 45 of the Act, any previous assessment by a regulatory authority, in Australia or outside Australia, in relation to allowing or approving dealings with the GMO; and'.

(2) Section 10(1)(b)(v), 'a selective'—

omit, insert—

'an'.

10 Replacement of s 13 (Requirements for notifiable low risk dealings)

Section 13—

omit, insert—

'13 Requirements for notifiable low risk dealings

'(1) A person must not undertake a notifiable low risk dealing unless an institutional biosafety committee has—

(a) notified the regulator, in the form approved by the regulator, of the proposed dealing; and

(b) given the person and the project supervisor for the proposed dealing written notice that—

(i) the proposed dealing is a dealing of a kind mentioned in schedule 3, part 1; and

(ii) the institutional biosafety committee considers the personnel to be involved in the proposed dealing have appropriate training and experience; and

(iii) paragraph (a) has been complied with.

'(2) When undertaken, a notifiable low risk dealing must comply with each of the following requirements—

(a) the dealing must be conducted in a facility that is—

(i) certified by the regulator to at least physical containment level 2, or another containment level the regulator considers suitable for conducting the dealing; and

(ii) of a design the regulator considers suitable for the kind of dealing being undertaken;

(b) to the extent the dealing involves transporting a GMO, the transportation must be conducted in accordance with applicable technical and procedural guidelines, as in force from time to time under section 27(d) of the Act.

'(3) The regulator may, by written notice, require—

(a) the institutional biosafety committee that has notified the regulator of a proposed notifiable low risk dealing; or

(b) an entity involved with the conduct of a notifiable low risk dealing of which the regulator has been notified;

to give the regulator the further information about the dealing as the regulator requires in order to be satisfied that the dealing is a notifiable low risk dealing.

'(4) A committee or entity receiving notice under subsection (3) must, by the end of the period stated in the notice, give the regulator the information required by the notice.'.

11 Amendment of s 39 (Record of GMO and GM product dealings)

(1) Section 39(2)(c)(ii), 'GM product;'—

omit, insert—

'GMO from which the GM product is derived;'.

(2) Section 39(3), definition *applicable Act*—

omit, insert—

'***applicable Act*** means the applicable Act under regulation 39 of the Commonwealth regulations.'.

12 Replacement of pt 8 (Transitional)

Part 8—

omit, insert—

‘Part 8 Transitional provision for Gene Technology Amendment Regulation (No. 1) 2007

‘41 Transitional provision for notifiable low risk dealings carried on by same person

‘(1) The purpose of this section is to enable a person (the ***affected person***) who conducted a relevant dealing before 31 March 2007 to apply for a GMO licence for the relevant dealing.

‘(2) Subject to subsection (3), the relevant dealing continues to be a notifiable low risk dealing under the Act, part 6, division 2 if the dealing is carried on by the affected person.

‘(3) Subsection (2) stops applying to the affected person on the earlier of the following—

(a) the day on which a GMO licence is issued to the affected person for the relevant dealing;

(b) 31 March 2008.

‘(4) In this section—

relevant dealing means a dealing that—

(a) was a notifiable low risk dealing before 31 March 2007; and

(b) is now a dealing requiring a GMO licence.

Note 1—

This section differs from regulation 4 of the *Gene Technology Amendment Regulations 2006 (No. 1)* (Cwlth).

Note 2—

This part does not appear in the Commonwealth regulations.’.

13 Replacement of schs 1–4

Schedules 1 to 4—

omit, insert—

‘Schedule 1A Techniques that are not gene technology

section 4

1 somatic cell nuclear transfer, if the transfer does not involve genetically modified material

2 electromagnetic radiation-induced mutagenesis

3 particle radiation-induced mutagenesis

4 chemical-induced mutagenesis

5 fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human

6 protoplast fusion, including fusion of plant protoplasts

7 embryo rescue

8 in-vitro fertilisation

9 zygote implantation

10 a natural process, if the process does not involve genetically modified material

Examples of a natural process for item 10—

- conjugation
- transduction
- transformation
- transposon mutagenesis

‘Schedule 1 Organisms that are not genetically modified organisms

section 5

1 A mutant organism in which the mutational event did not involve the introduction of foreign nucleic acid (that is, non-homologous DNA, usually from another species).

2 A whole animal, or human being, modified by the introduction of naked recombinant nucleic acid (for example, a DNA vaccine) into its somatic cells, if the introduced nucleic acid is incapable of giving rise to infectious agents.

3 Naked plasmid DNA that is incapable of giving rise to infectious agents when introduced into a host cell.

6 An organism resulting from an exchange of DNA if—

(a) the donor species is also the host species; and

(b) the vector DNA does not contain any heterologous DNA.

7 An organism resulting from an exchange of DNA between the donor species and the host species if—

(a) the exchange can happen by naturally occurring processes; and

(b) the donor species and the host species are micro-organisms that—

(i) satisfy the criteria in AS/NZS 2243.3:2002—Safety in laboratories—Microbiological aspects and containment facilities for classification as risk group 1; and

(ii) are known to exchange nucleic acid by a natural physiological process; and

(c) the vector used in the exchange does not contain heterologous DNA from an organism other than an organism involved in the exchange.

‘Schedule 2 Dealings exempt from licensing

section 6(1)(a) and (b)

Note—

Section 6(1) states other requirements for exempt dealings.

‘Part 1 Exempt dealings

1 A dealing with a genetically modified laboratory mouse or genetically modified laboratory rat, unless—

(a) an advantage is conferred on the animal by the genetic modification; or

(b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.

2 A dealing with a genetically modified *Caenorhabditis elegans*, unless—

(a) an advantage is conferred on the animal by the genetic modification; or

(b) as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent.

3 A dealing with an animal into which genetically modified somatic cells have been introduced, if—

(a) the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and

(b) the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.

4(1) Subject to subsections (2) and (3), a dealing involving a host/vector system mentioned in part 2 of this schedule and producing no more than 10L of GMO culture in each vessel containing the resultant culture.

(2) The donor nucleic acid—

(a) must satisfy 1 of the following requirements—

(i) it must not be derived from organisms implicated in, or with a history of causing, disease in human beings, animals, plants or fungi;

(ii) it must be characterised and not known to alter the host range or mode of transmission, or to increase the virulence, pathogenicity or transmissibility of the host or vector; and

(b) must not code for a toxin with an LD_{50} of less than 100μg/kg; and

(c) must not code for a toxin with an LD_{50} of 100μg/kg or more, if the intention is to express the toxin at high levels; and

(d) must not be uncharacterised nucleic acid from a toxin-producing organism; and

(e) must not include a viral sequence, unless the donor nucleic acid—

(i) is missing at least 1 gene essential for viral multiplication that—

(A) is not available in the cell into which the nucleic acid is introduced; and

(B) will not become available during the dealing; and

(ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions.

(3) If the vector is able to transduce human cells, the donor nucleic acid must not confer an oncogenic modification.

5 A dealing involving shotgun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in part 2, item 1 of this schedule if the donor nucleic acid is not derived from—

(a) a pathogen; or

(b) a toxin-producing organism.

‘Part 2 Host/vector systems for exempt dealings

Column 1 Item	Column 2 Class	Column 3 Host	Column 4 Vector
1	bacteria	*Escherichia coli* K12, *E. coli* B or *E. coli* C—a derivative that does not contain— (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid	1 non-conjugative plasmids 2 bacteriophage— (a) lambda; (b) lambdoid; (c) Fd or F1 (for example, M13) 3 none (non-vector systems)
		Bacillus—specified species—asporogenic strains with a reversion frequency of less than 10^{-7}— (a) *B. amyloliquefaciens;* (b) *B. licheniformis;* (c) *B. pumilus;* (d) *B. subtilis;* (e) *B. thuringiensis*	1 non-conjugative plasmids 2 plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or another pathogenic strain of *Bacillus* 3 none (non-vector systems)
		Pseudomonas putida—strain KT 2440	1 non-conjugative plasmids including certified plasmids—pKT 262, pKT 263, pKT 264 2 none (non-vector systems)
		Streptomyces—specified species— (a) *S. aureofaciens*; (b) *S. coelicolor;* (c) *S. cyaneus*; (d) *S. griseus;* (e) *S. lividans;* (f) *S. parvulus;* (g) *S. rimosus;* (h) *S. venezuelae*	1 non-conjugative plasmids 2 certified plasmids—SCP2, SLP1, SLP2, PIJ101 and derivatives 3 actinophage phi C31 and derivatives 4 none (non-vector systems)

Column 1 Item	Column 2 Class	Column 3 Host	Column 4 Vector
		Agrobacterium radiobacter *Agrobacterium rhizogenes*—disarmed strains *Agrobacterium tumefaciens*—disarmed strains	1 non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2 none (non-vector systems)
		Lactobacillus *Oenoccus oeni* syn. *Leuconostoc oeni* *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicate* *Rhizobium* (including the genus *Allorhizobium)* *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis* *Vibrio cholerae* CVD103-HgR	1 non-conjugative plasmids 2 none (non-vector systems)
2	fungi	*Neurospora crassa*—laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Kluyveromyces lactis* *Trichoderma reesei*	1 all vectors 2 none (non-vector systems)
3	slime moulds	*Dictyostelium* species	1 *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2 none (non-vector systems)

Column 1 Item	Column 2 Class	Column 3 Host	Column 4 Vector
4	tissue culture	animal or human cell cultures (including packaging cell lines)	1 non-conjugative plasmids 2 non-viral vectors or defective viral vectors (other than a retroviral vector that is able to transduce human cells) 3 avipox vectors (attenuated vaccine strains) 4 baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus 5 none (non-vector systems)
		plant cell cultures	1 non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors, in *Agrobacterium tumefaciens, Agrobacterium radiobacter* or *Agrobacterium rhizogenes* 2 non-pathogenic viral vectors 3 none (non-vector systems)

‘Schedule 3 Notifiable low risk dealings in relation to a GMO

section 12(1)(a)

‘Part 1 Dealings that are notifiable low risk dealings

Note—

Under section 12(1), a dealing mentioned in this part is not a notifiable low risk dealing if it is also mentioned in part 2 of this schedule.

'1.1 Kinds of dealings

The following kinds of dealings are notifiable low risk dealings—

(a) a dealing involving whole animals, including non-vertebrates, that—

(i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and

(ii) does not involve any of the following—

(A) a genetically modified laboratory mouse;

(B) a genetically modified laboratory rat;

(C) a genetically modified *Caenorhabditis elegans*;

(aa) a dealing involving a genetically modified laboratory mouse or genetically modified laboratory rat, if—

(i) the genetic modification confers an advantage on the animal; and

(ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification;

(ab) a dealing involving a genetically modified *Caenorhabditis elegans*, if—

(i) the genetic modification confers an advantage on the animal; and

(ii) the animal is not capable of secreting or producing an infectious agent as a result of the genetic modification;

(b) a dealing involving a genetically modified plant, including a genetically modified flowering plant, if the dealing occurs in a facility designed to prevent the escape from the facility of—

(i) pollen, seed, spores or other propagules which may be produced in the course of the dealing; and

(ii) invertebrates capable of carrying the material mentioned in subparagraph (i);

(ba) a dealing involving a genetically modified flowering plant, if, before flowering, all inflorescences are entirely enclosed in bags designed to prevent escape of viable pollen and seed;

(c) a dealing involving a host and vector not mentioned as a host/vector system in schedule 2, part 2, if—

(i) the host has not been implicated in, or had a history of causing, disease in human beings, animals, plants or fungi; and

(ii) the vector has not been implicated in, or had a history of causing, disease in human beings, animals, plants or fungi;

(d) a dealing involving a host and vector not mentioned as a host/vector system in schedule 2, part 2, if—

(i) either—

(A) the host has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; or

(B) the vector has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; and

(ii) the donor nucleic acid is characterised and is not known to alter the host range or mode of transmission, or to increase the virulence, pathogenicity or transmissibility of the host or vector;

(e) a dealing involving a host/vector system mentioned in schedule 2, part 2, if the donor nucleic acid—

(i) codes for a pathogenic determinant; or

(ii) is uncharacterised nucleic acid from an organism that has been implicated in, or has a history of causing, disease in human beings, animals, plants or fungi; or

(iii) in a case in which the vector is able to transduce human cells—confers an oncogenic modification;

(f) a dealing involving a host/vector system mentioned in schedule 2, part 2 and producing more than 10L of GMO culture in each vessel containing the resultant culture, if—

(i) the dealing is undertaken in a facility certified by the regulator—

(A) as a large scale facility; and

(B) to at least physical containment level 2; and

(ii) the donor nucleic acid satisfies the conditions stated in schedule 2, part 1, section 4;

(g) a dealing involving complementation of knocked-out genes, if the complementation does not alter the host range or mode of transmission, or increase the virulence, pathogenicity, or transmissibility of the host above that of the parent organism before the genes were knocked-out;

(h) a dealing involving shotgun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in schedule 2, part 2, item 1, if the donor nucleic acid is derived from—

(i) a pathogen; or

(ii) a toxin-producing organism;

(i) a dealing involving introducing a replication defective retroviral vector able to transduce human cells into a host mentioned in schedule 2, part 2 if the donor nucleic acid is incapable of correcting a defect in the vector leading to production of replication competent virions.

‘Part 2 Dealings that are not notifiable low risk dealings

Note 1—

The following list qualifies the list in part 1 and is not an exhaustive list of dealings that are not notifiable low risk dealings.

Note 2—

A dealing that is not a notifiable low risk dealing, or an exempt dealing, may be undertaken only by a person who is licensed under the Act for the dealing (see section 32 of the Act).

'2.1 Kinds of dealings

A dealing of any of the following kinds, or involving a dealing of any of the following kinds, is not a notifiable low risk dealing—

(a) a dealing (other than a dealing mentioned in this schedule, part 1, section 1.1(h)) involving cloning of nucleic acid coding for a toxin with an LD_{50} of less than 100μg/kg;

(b) a dealing involving high level expression of toxin genes, even if the LD_{50} is 100μg/kg or more;

(c) a dealing (other than a dealing mentioned in this schedule, part 1, section 1.1(h)) involving cloning of uncharacterised nucleic acid from a toxin-producing organism;

(d) unless the viral vector is part of a host/vector system mentioned in schedule 2, part 2 or this schedule, part 1, section 1.1(i)—a dealing involving donor nucleic acid in a viral vector if the donor nucleic acid—

(i) confers an oncogenic modification; or

(ii) codes for—

(A) immunomodulatory molecules; or

(B) cytokines; or

(C) growth factors, or components of a signal transduction pathway that, when expressed, may lead to cell proliferation;

(e) a dealing involving, as host or vector, a micro-organism that has been implicated in, or has a history of causing, disease in humans, animals, plants or fungi, unless—

(i) the host/vector system is a system mentioned in schedule 2, part 2; or

(ii) the donor nucleic acid is characterised and is not known to alter the host range or mode of transmission, or to increase the virulence, pathogenicity or transmissibility of the host or vector; or

(iii) the dealing is a dealing mentioned this schedule, part 1, section 1.1(g);

(f) a dealing involving the introduction, into a micro-organism, of nucleic acid coding for a pathogenic determinant, unless—

(i) the dealing is a dealing mentioned in this schedule, part 1, section 1.1(g); or

(ii) the micro-organism is a host mentioned in schedule 2, part 2;

(g) a dealing involving the introduction into a micro-organism, other than a host mentioned in schedule 2, part 2, of genes whose expressed products have a heightened risk of inducing an auto-immune response;

(h) a dealing involving use of a viral or viroid genome, or fragments of a viral or viroid genome, to produce a novel replication competent virus with altered host range or mode of transmission, or increased virulence, pathogenicity or transmissibility in relation to any parent or donor organism;

(i) a dealing involving a lentiviral vector able to transduce human cells unless—

(i) all structural and accessory genes have been removed from the vector to render it incapable of replication or assembly into a virion without these functions being supplied *in trans*; and

(ii) the vector includes a deletion that results in a transcriptionally inactive vector which, even when packaging functions are supplied *in trans*, cannot be converted into full length viral RNA; and

(iii) the packaging cell line and packaging plasmids used contain only viral genes *gag, pol, rev* and a gene coding for an envelope protein;

(j) a dealing involving a genetically modified animal, plant or fungus capable of secreting or producing infectious agents as a result of the genetic modification;

(k) a dealing producing more than 10L of GMO culture in each vessel containing the resultant culture, other than a dealing mentioned in this schedule, part 1, section 1.1(f);

(l) a dealing inconsistent with a policy principle issued by the Ministerial council;

(m) a dealing involving the intentional introduction of a GMO into a human being;

(n) a dealing involving a genetically modified pathogenic organism, if the practical treatment of any disease or abnormality caused by the organism would be impaired by the genetic modification.'.

14 Amendment of sch 5 (Dictionary)

(1) Schedule 5, definitions *advice to proceed, code, division 3 application, division 4 application* and *genetic manipulation advisory committee*—

omit.

(2) Schedule 5—

insert—

'***AS/NZS*** means a joint Standards Australia and Standards New Zealand standard.

code, for a toxin or other product, means specify the amino acid sequence of the toxin or other product.

genetically modified laboratory mouse means a laboratory strain of mouse of the species *Mus musculus* that has been modified by gene technology.

genetically modified laboratory rat means a laboratory strain of rat of either the species *Rattus rattus* or *Rattus norvegicus* that has been modified by gene technology.

infectious agent means an agent that is capable of entering, surviving in, multiplying, and potentially causing disease in, a susceptible host.

known means known within the scientific community.

non-conjugative plasmid, for schedule 2, part 2, means a plasmid that is not self-transmissible, and includes, but is not limited to, a non-conjugative form of a following plasmid—

(a) a bacterial artificial chromosome (BAC);

(b) a cosmid;

(c) a P1 artificial chromosome (PAC);

(d) a yeast artificial chromosome (YAC).

non-vector system, for schedule 2, part 2, means a system by which donor nucleic acid is introduced (including, for example, by electroporation or particle bombardment) into a host in the absence of a nucleic acid-based vector.

Examples of a nucleic acid-based vector—

- a plasmid
- a viral vector
- a transposon

nucleic acid means DNA or RNA, or both DNA and RNA, of any length.

oncogenic modification means a genetic modification capable of inducing unregulated cell proliferation in a vertebrate cell.

packaging cell line means an animal or human cell line containing 1 or more genes that when expressed *in trans* are necessary and sufficient to complement packaging defects of a replication defective viral vector in order to produce packaged replication defective virions.

pathogenic, for an organism, means having the capacity to cause disease or abnormality.

pathogenic determinant means a characteristic having the potential to increase the capacity of a host or vector to cause disease or abnormality.

plasmid means a DNA molecule capable of autonomous replication and stable extrachromosomal maintenance in a host cell.

toxin means a substance that is toxic to a vertebrate.

toxin-producing organism means an organism producing toxin with an LD_{50} of less than 100µg/kg.

transduce, for a viral vector or viral particle, means enter an intact cell by interaction of the viral particle with the cell membrane.'.

(3) Schedule 5, definition *advantage*, 'adult animal'—

omit, insert—

'organism'.

(4) Schedule 5, definition *characterised*, 'DNA'—

omit, insert—

'nucleic acid'.

(5) Schedule 5, definition *shotgun cloning*, ', for mammalian DNA,'—

omit.

(6) Schedule 5, definition *shotgun cloning*, 'the DNA'—

omit, insert—

'nucleic acid'.

ENDNOTES

1 Made by the Governor in Council on 29 March 2007.

2 Notified in the gazette on 30 March 2007.

3 Laid before the Legislative Assembly on . . .

4 The administering agency is the Department of State Development.